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LARRY MCCLEARY

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Patent Application Serial No. 10/816,674))
*	Group Art Unit: 1618
Filing Date: July 10, 2003)) Examiner: Ebrahim, Nabila G
For: SALAD DRESSING WITH () WEIGHT LOSS SUPPLEMENT ()	Docket No: 23604.0102PTUS
Inventor: Carl A. Forest	Confirmation No.: 2594

DECLARATION OF EDWARD LARRY McCLEARY

- 1, Edward Larry McCleary, hereby declare:
- 1. I am a pediatric neurosurgeon. I am also involved in the business of nutritional supplements, which includes product development of nutritional supplement combinations for the brain and nervous system. All statements made herein of my own knowledge are true, and all statements made on information and belief are believed to be true.
- 2. I have worked for over 25 years as a physician (MD). I am licensed to practice medicine and surgery (pediatric neurosurgery) in Colorado. I have published numerous professional papers and have made national and international presentations on various subjects pertaining to the field of pediatric neurosurgery. These topics span the fields of surgical technique, intra-operative real time imaging, spinal cord tumors, adoptive immuno-therapy for brain tumors, cerebral trauma, monitoring and therapy of intracranial hypertension, and metabolic aspects of neurosurgery. I have been involved in the training of medical, surgical, and neurosurgical residents and house staff. I have been an active member of the Childrens' Cancer Study Group (now Childrens' Oncology Group), and have participated in the design and implementation of cancer protocols.
 - My formal training includes:
 Dartmouth College, BA, 1971 (Rufus Choate Scholar)

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Boston University, 1971-73, Theoretical Physics
State University of NY at Buffalo, MD, 1979 (AOA)
University of Minnesota Medical School, Surgical Residency 1980
Bellevue-New York University, Neurosurgery residency 1980-86

- 4. Following my neurosurgical training, I was a pediatric neurosurgeon at Denver Childrens' Hospital, where I was Acting Chief of Neurosurgery for 4 years. During the past decade, I have intensively studied the use and development of nutritional supplement combinations for weight loss therapy. I have designed a variety of weight loss nutritional supplements and helped conduct human clinical trials of nutritional supplement combinations for the treatment of various conditions associated with excessive weight.
- 5. I have developed a unique method of analyzing and treating overweight conditions which treats multiple metabolic mechanisms, which I refer to as metabolic pathways, and thereby treats the underlying causes of overweight conditions. I am recognized as an expert in this area, particularly since one of the supplements I developed has been clinically proven to be seven times more effective than the best pharmaceutical weight loss product.
- 6. I have read the currently pending claims of the Application, as well as the Office Action dated April 2, 2007 (hereinafter, "the Office Action").
- 7. I submit this Declaration to present to the Examiner, in an authenticated manner, facts concerning the patentability of the claims.
- 8. I am the inventor of U.S. Patent No. 6579866 (the '866 patent) over which the present claims are rejected.
- 9. The Office Action states that the '866 patent teaches that the supplement can be administered orally as suspensions in water, powder, chewable wafer and does not exclude using in any food or drink. This is not correct.
- 10. In writing the '866 patent, I only contemplated conventional methods of administration of solid medicines which I was familiar with from my long background as a medical doctor, and specifically did not teach the combination with foods and drinks.

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and in particular, salad dressings.

- 11. The suspensions in water and references to powder referred to in the '866 patent is a conventional way of administering medicines by converting a solid substance to powder and stirring it into water.
- 12. The chewable wafers referred to in the '866 patent is a conventional form of administering medicine, also based on my long experience as a medical doctor, and involves only the combination of the medicine with an inert base and, sometimes a flavoring agent, and does not suggest putting the medicine in salad dressing.
- 13. To one skilled in the art of administering medicines and supplements, the administration by suspensions in water, powders and chewable wafers does exclude adding it to any food or drink other than water and specifically excludes the combination with salad dressings. This is because no physician would prescribe the administration of a medicine in salad dressing. Since this has not been certified (as of yet) it would be considered unacceptable. In my entire career I have never heard of this.
- 14. In the present Office Action and the prior Office Action, the Examiner argues that there is no apparent reason that why the Applicant was prevented from presenting claims in the '866 patent corresponding to those in the present application. This is absolutely wrong.
- 15. For one obvious reason, the present inventor was not an inventor of the '866 patent,
- 15. Further, in writing the '866 application I was thinking clinically as a medical doctor. As I mentioned above, no medical doctor would prescribe administration of a medicine or supplement in salad dressing.
- 16. The only reason why the present application contains the present claims is that I disclosed my supplements to a person not constrained by the thinking box in which medical doctors by training are constrained, which persons are my co-inventors.
- 17. Moreover, the combination of the weight loss supplement with salad dressing produces completely unexpected results.

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- 18. I have taste tested the particular supplement disclosed and claimed in the '866 patent as well as various particular ingredients claimed in the present claims, such as L-aspartic acid and L-carnitine, in combination with salad dressing. I was completely amazed at the results.
- 19. The taste of my supplement disclosed and claimed in the '866 patent actually enhances the taste of the salad dressing. The supplement has a mild acidic flavor, similar to, but lighter and more sophisticated than, lemon. The taste was extremely pleasant.
- 20. The above result could not have been predicted by reading my '688 patent and was completely unexpected.
- 21. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like are punishable by fine or imprisonment, or both, under 18 U.S.C. §1001, and that such willful false statements may jeopardize the validity of the Application or any patent issued thereon.

Date

Edward Larry McCleary